REMARKS

INTRODUCTORY COMMENTS:

In the Office Action under reply, the first Action concerning the present application, the specification and claims were subject to several grounds of objection and rejection. Specifically, the claims were objected to for containing certain informalities. The claims stand rejected:

(1) under 35 U.S.C. § 102(a) as anticipated by PCT Publication WO00/13685, inventor Dannenberg ("Dannenberg");

(2) under 35 U.S.C. § 102(a) as anticipated by U.S. Patent No. 6,022,901 to Goodman ("Goodman");

(3) under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,414,037 to Pezzuto et al. ("Pezzuto");

(4) under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,329,422 to Fischer et al. ("Fisher"); and

(5) under 35 U.S.C. § 103(a) as obvious over Fischer et al. in view Goldberg et al. (Journal Article), Pezzuto et al., Goodman & Gilman's Ninth Edition, and the American Drug Index, Facts and Comparisons (claims 1-10, 16, 17, 21-23, and 26-29).

Applicants acknowledge with appreciation the Examiner's indication of allowable subject matter in claims 19 and 20.

The aforementioned grounds of rejection are addressed in part by way of the above amendments and are otherwise traversed below. With this amendment, applicants have amended claims 1, 21, 22, 27, 29 and 30, and added new claims 31-37. Thus, claims 1-37 are now pending and under examination.

THE AMENDMENTS AND NEW CLAIMS:

Claims 1, 21, 22 and 27 have been amended to correct informalities pointed out by the Examiner in the "claim objections." Claim 29 has been amended to specify that it is a pharmaceutical formulation for pulmonary administration, and comprises a carrier suitable for pulmonary administration. Support for the amendment may be found throughout the application,

particularly at page 14, line 13 through page 18, line 2. Claim 30 has been amended to specify that the formulation is a dry powder formulation for pulmonary administration. Support for this amendment can also be found at the aforementioned passages of the specification.

New claims 31-37 have been added. Support for the new claims can be found in the claims and specification as filed.

OBJECTION TO THE OATH OR DECLARATION:

The Examiner stated that the oath or declaration is defective because it does not identify the mailing address of each inventor. The Examiner indicated that the mailing address can be provided in an application data sheet or a supplemental oath or declaration.

In response, applicants have supplied an application data sheet to correct this omission, pursuant to 37 C.F.R. §§ 1.63(c) and 1.76.

THE REJECTION UNDER 35 U.S.C. § 102(a) OVER DANNENBERG:

Claim 30 stands rejected under 35 U.S.C. §102(a) over Dannenberg. The Examiner stated that Dannenberg discloses lozenges containing resveratrol, and teaches methods for treating inflammatory diseases of the head and neck by administering compositions containing resveratrol, including lozenges, rinses or oral sprays. To support this rejection, the Examiner cited Example IV, page 24; as well as page 18, lines 21-22; page 19; and claims 1 and 4. Applicants respectfully traverse this rejection.

Dannenberg describes the use of a selective inhibitor of cyclooxygenase-2 administered via systemic or local routes for diseases of the head and neck, such as the treatment of sore throat caused by tonsillitis or pharyngitis (page 18, lines 16-22). The selective inhibitors of cyclooxygenase-2 are set forth in a "laundry list" of 205 cyclooxygenase-2 inhibitors, which does not include resveratrol. On page 19, Dannenberg states that inhibitors of cyclooxygenase-2 from natural sources are used a topical therapy for sore throats, and that the agent is administered as a lozenge, oral rinse or spray, or can be administered systemically for the treatment of sore throat or sinusitis. Example IV describes the treatment of a sore throat using lozenges containing resveratrol.

Claim 30 is directed to a dry powder pharmaceutical formulation for pulmonary administration, comprising an active agent selected from the group consisting of resveratrol, pharmacologically acceptable salts, esters, amides, prodrugs and analogs thereof, and a carrier suitable for pulmonary drug administration, wherein the pharmaceutical formulation is a dry powder formulation for pulmonary administration. These features are not disclosed or suggested by Dannenberg.

Applicants respectfully submit that Dannenberg does not disclose or suggest the subject matter of claim 30, as amended. Therefore, applicants respectfully request that the rejection of claim 30 be reconsidered and withdrawn.

THE REJECTION UNDER 35 U.S.C. § 102(a) OVER GOODMAN:

Claim 30 stands rejected under 35 U.S.C. §102(a) over Goodman. The Examiner stated that Goodman discloses compositions containing resveratrol, cis-resveratrol, trans-resveratrol and salts, esters, amides, prodrugs or analogs thereof where the compositions may be in a form suitable for nasal aerosol or inhalation. To support this rejection, the Examiner cited the abstract, col. 7, line 66 to col. 8, line 7 and lines 25-27.

Applicants respectfully traverse this rejection. Goodman is directed to a method for preventing or treating restenosis and for preventing the recurrence or progression of coronary heart disease. Although Goodman involves administration of resveratrol and its salts, esters, amides, prodrugs or analogs, Goodman does not teach or suggest the subject matter of claim 30. Specifically at col. 7, lines 66 to col. 8, line 7, Goodman states that the compositions prepared as solutions in saline can be administered by nasal aerosol or inhalation. Further, at col. 8, lines 25-27, cited by the Examiner, Goodman merely discusses formulations for buccal administration.

In contrast, claim 30 recites a dry powder pharmaceutical formulation for pulmonary administration. Applicants respectfully point out that administration of a saline solution containing resveratrol by nasal aerosol or inhalation, as taught by Goodman, is distinguishable from the presently claimed dry powder formulation for pulmonary administration.

Applicants respectfully submit that Goodman does not disclose or suggest the subject matter of claim 30, as amended. Therefore, applicants respectfully request that the rejection of claim 30 be reconsidered and withdrawn.

THE REJECTION UNDER 35 U.S.C. § 102(e) OVER PEZZUTO:

Claim 29 stands rejected under 35 U.S.C. §102(e) over Pezzuto. The Examiner stated that Pezzuto discloses compositions for treating humans or animals suffering from skin disorders, wherein the compositions include resveratrol and salts, esters, amides, prodrugs or analogs thereof, and anti-inflammatory agents or antibiotics. To support this rejection, the Examiner cited the abstract, col. 10, lines 16-19 and lines 45-50.

Applicants respectfully traverse this rejection. Applicants respectfully point out that although Pezzuto describes formulations containing resveratrol and its salts, esters, amides, prodrugs and analogs, along with anti-inflammatory agents or antibiotics, the formulations of Pezzuto are intended for topical application to the skin and treatment of skin disorders. Specifically, the abstract, and col. 10, lines 16-19 and lines 45-50 describe pharmaceutical formulations containing resveratrol and additional active agents for treating or preventing skin conditions. In addition, at col. 10, lines 60-63, Pezzuto clearly indicates that the formulations are administered topically to the skin or mucosal tissue as an ointment, lotion, cream, microemulsion, gel, or solution.

In contrast, claim 29, as amended, is directed to a pharmaceutical formulation for pulmonary administration. In addition, claim 29 further comprises a carrier suitable for pulmonary drug administration. Therefore, claim 29 is distinguishable over the subject matter described by Pezzuto.

Applicants therefore respectfully submit that Pezzuto does not disclose or suggest the subject matter of claim 29, as amended. Applicants respectfully request that the rejection of claim 29 be reconsidered and withdrawn.

THE REJECTION UNDER 35 U.S.C. § 102(e) OVER FISCHER:

Claim 30 stands rejected under 35 U.S.C. §102(e) over Fischer. The Examiner stated that Fischer discloses compositions for treating cystic fibrosis, chronic bronchitis or asthma, containing resveratrol and aerosol propellants useful for endopulmonary and/or intranasal inhalation administration. To support this rejection, the Examiner cited col. 6, line 58-67; col. 11, lines 47-60; col. 13, lines 24-30 and claim 28.

Claims 1, 11-15, 18, 24 and 25 were also rejected under 35 U.S.C. §102(e) over Fischer. The Examiner stated that Fischer discloses methods for treating cystic fibrosis, chronic bronchitis or asthma, wherein the methods include administering a composition containing flavones and resveratrol. The Examiner further stated that the compositions contain aerosol propellants useful for endopulmonary and/or intranasal inhalation or the compositions may be administered orally. To support these rejections, the Examiner cited col. 6, line 58-67; col. 11, lines 47-60; col. 12, lines 61-63; col. 13, lines 24-30 and claim 28.

Applicants respectfully traverse these rejections. With respect to claim 30, applicants respectfully point out that Fischer does not teach or suggest the subject matter of claim 30. Fischer is directed to a method of treating diseases characterized by defective chloride transport, specifically cystic fibrosis, by administering flavones, isoflavones and other polyphenolic compounds that are capable of stimulating CFTR-mediated chloride transport in epithelial tissues. *See* col. 6, lines 58-67. Other diseases with excessive accumulation of mucous were also cited, such as chronic bronchitis and asthma. Fischer, at col. 11, lines 47-60 teaches that an example of one "other polyphenolic compound" is resveratrol. At col. 13, lines 24-30, Fischer describes administration of the compounds "as a pressurized aerosol or nebulized formulation to the patient's lungs via inhalation." At lines 30-37, Fischer describes the formulations as containing water, with or without cosolvents, surfactants, and stabilizers, and antimicrobial agents. Fischer also states that the "compositions are also generally filtered and sterilized, and may be lyophilized to provide enhanced stability and to improve solubility." Further, at lines 37-40, Fischer states that the compositions are administered in an amount and a frequency effective to inhibit or alleviate the symptoms of cystic fibrosis, and at lines 51-53, Fischer states that "[c]ompositions administered as an aerosol are generally designed to provide a final

concentration of about 10 to about 50 μM at the airway surface." Finally, claim 28 recites a method for enhancing chloride transport in epithelial cells by contacting epithelial cells with genistein and a compound that may be resveratrol.

Applicants respectfully submit that claim 30 is distinguishable over Fischer. Specifically, Fischer does not teach or suggest administration of resveratrol as a dry powder formulation for pulmonary inhalation. Although Fischer appears to describe administration of a formulation containing resveratrol by inhalation, the formulations described by Fischer are aerosol formulations, containing the flavones or isoflavones or other polyphenolic compounds as solutions to be aerosolized or nebulized. There is no teaching or suggestion of a dry powder formulation in the disclosure of Fischer, or of administering a formulation containing resveratrol by dry powder inhalation. Therefore, claim 30 is distinguishable over the disclosure of Fischer.

With respect to claims 1, 11-15, 18, 24 and 25, applicants also respectfully point out that Fischer does not teach or suggest the subject matter of these claims. As discussed above, Fischer is directed to a method of treating diseases characterized by defective chloride transport, specifically cystic fibrosis, by administering flavones, isoflavones and other polyphenolic compounds that are capable of stimulating CFTR-mediated chloride transport in epithelial tissues. *See* col. 6, lines 58-67. Other diseases with excessive accumulation of mucus were also cited, such as chronic bronchitis and asthma. Fischer, at col. 11, lines 47-60 teaches that an example of one "other polyphenolic compound" is resveratrol. Fischer also notes that chloride transport in epithelial cells can be enhanced by contacting epithelial cells with genistein and a compound that may be resveratrol. The additional cited portion of Fischer at col. 12, lines 61-63 states only that administration may be achieved by a variety of different routes, and that oral administration of a composition such as a pill, capsule or suspension is preferred.

Fischer is directed to a method for enhancing chloride transport as a way of alleviating the excessive mucous found in patients suffering from cystic fibrosis. In contrast, instant independent claim 1, upon which the rejected claims depend, recites a method for treating a patient suffering from or predisposed to developing an inflammatory respiratory disorder comprising administering resveratrol, pharmacologically acceptable salts, esters, amides, prodrugs or analogs thereof, and combinations thereof. The inflammatory respiratory disorders

disclosed in the present specification and claimed in the pending claims are different from disorders caused by defective chloride transport, discussed and claimed in Fischer. Although asthma is discussed in Fischer as a disorder associated with excessive accumulation of mucous, it is well known that asthma is an inflammatory disorder, and any excessive mucous is due to the inflammation, not to any deficiency in the chloride transport of the epithelial tissues of the asthmatic lung. In any event, even if asthma were considered to be a "condition responsive to stimulation of chloride transport" as phrased by Fischer, the treatment of excessive mucous would have no bearing on the treatment of an inflammatory respiratory disorder, as presently claimed.

Applicants therefore respectfully submit that Fischer does not disclose or suggest the subject matter of claims 1, 11-15, 18, 24, 25 and 30. Therefore, applicants respectfully request that the rejection of claims 1, 11-15, 18, 24, 25 and 30 be reconsidered and withdrawn.

THE REJECTION UNDER 35 U.S.C. § 103(a) OVER FISCHER IN VIEW GOLDBERG, PEZZUTO, GOODMAN & GILMAN'S NINTH EDITION, AND THE AMERICAN DRUG INDEX, FACTS AND COMPARISONS:

Claims 1-10, 16, 17, 21-23, 26-28 and 29 stand rejected under 35 U.S.C. §103(a) over Fischer in view Goldberg, Pezzuto, Goodman & Gilman's Ninth Edition, and the American Drug Index, Facts and Comparisons. The Examiner conceded that Fischer does not specifically disclose administration of the claimed analogs or cis- or trans-isomers of resveratrol. The Examiner also conceded that Fischer does not teach that resveratrol is an anti-inflammatory agent. However, the Examiner cited Goldberg as teaching that resveratrol contained in plants has been used in Japan for the treatment of inflammatory disorders (citing page 159, second col., first paragraph). The Examiner also cited Pezzuto for teaching that salts, esters, prodrugs, amides or analogs of resveratrol as well as trans-resveratrol, cis-resveratrol, trans- or cis-resveratrol glucoside are biologically active compounds, i.e. have pharmaceutical activity (abstract and col. 1, lines 29-35) and further that resveratrol has antioxidant and anti-inflammatory properties (col. 3, lines 15-25).

The Examiner stated that it would have been obvious to one of ordinary skill in the art to modify the methods of Fischer to include the trans or cis isomers of resveratrol because in view of Goldberg and Pezzuto, one skilled in the art would reasonably expect these isomers to be equally effective in treating cystic fibrosis, chronic bronchitis or asthma. The Examiner alleged that this modification would have been motivated by the reasoned expectation of successfully treating patients suffering from cystic fibrosis, chronic bronchitis or asthma.

With respect to claim 29, the Examiner conceded that Fischer does not disclose combining resveratrol with glucocorticoids. However, the Examiner alleged that Goodman & Gilman discloses that glucocorticoids are known to be useful in treating asthma, therefore it would have been obvious to modify the compositions of Fischer to include glucocorticoids because such a modification would have been motivated by the reasoned expectation that the combined effect of resveratrol and glucocorticoids would successfully treat patients suffering from asthma.

With respect to claims 21-23, the Examiner alleged that in view of Goldberg and Pezzuto, one of ordinary skill in the art would reasonably expect resveratrol and its anti-inflammatory properties to treat inflammation resulting from occupational or environmental exposure to smoke, dust or allergens.

With respect to claims 16 and 17, the Examiner conceded that Fischer does not disclose treating atopic asthma. However, the Examiner alleged that one skilled in the art would "reasonably expect resveratrol which is capable of treating asthma to be equally effective in treating atopic or non-atopic asthma."

Finally with respect to claims 26-28, the Examiner stated that Pezzuto discloses pharmaceutical compositions containing resveratrol and anti-inflammatory agents or antibiotics. Therefore, the Examiner alleged, it would have been obvious to one of ordinary skill in the art to modify the methods of Fischer to include additional anti-inflammatory agents or antibiotics (as suggested by Pezzuto) because one skilled in the art would reasonably expect the anti-inflammatory agents or antibiotics to treat or prevent any inflammation or infections that may result from or accompany the asthma, bronchitis or cystic fibrosis. The Examiner alleged that it would also have been obvious to modify the methods of Fischer to additionally administer

bronchodilators such as theophylline and salmetrol xinofoate, as allegedly taught by the American Drug Index, or the use of antiasthmatics such as cromolyn sulfate and beta-adrenergic agonists, as taught by Goodman & Gilman (citing pages 666-668) because one of ordinary skill in the art would reasonably expect these bronchodilators and/or the antiasthmatics to be equally effective in treating patients suffering from asthma.

Applicants respectfully traverse these rejections. To establish *prima facie* obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success, and third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Fischer is directed to a method for enhancing chloride transport in epithelial cells, and does not relate to inflammatory disorders. Specifically, Fischer aims to enhance chloride transport as a therapy for cystic fibrosis, because cystic fibrosis is caused by a defect in the chloride transport protein. The defect in chloride transport in patients suffering from cystic fibrosis is in what is termed the "cystic fibrosis transmembrane conductance regulator" (CFTR). This defect causes a reduced ability of epithelial cells to transport chloride, sodium and water, and results in the accumulation of excessive amounts of sticky mucous that is not readily removed from the patient's lungs. One goal of researchers seeking improved methods for treating cystic fibrosis is to find new methods for enhancing transport of chloride in epithelial cells. *See* Fischer, Background of the Invention.

Applicants respectfully submit that the combination of Fischer with any of the secondary references cited by the Examiner would not render the present claims obvious. Even when combined with the other references, Fischer would not teach or suggest all of the claim limitations. Independent claim 1 recites:

> A method for treating a patient suffering from or predisposed to developing an inflammatory respiratory disorder, comprising administering to the patient a pharmaceutical formulation that comprises a pharmaceutically acceptable carrier and a therapeutically effective amount of an active agent selected from the group consisting of resveratrol, pharmacologically acceptable salts, esters, amides, prodrugs or analogs thereof, and combinations of any of the foregoing.

Claims 2-10, 16, 17, 21-23, 26-28, dependent from claim 1, also are directed to a method for treating a patient suffering from or predisposed to developing an inflammatory respiratory disorder. The present claims are patentable over Fischer because the Fischer method for enhancing chloride transport does not suggest treating the disorder of claim 1. Fischer's treatment for cystic fibrosis or excessive mucous does not suggest treating the disorder of claim 1. So even in combination with the additional cited references, Fischer cannot teach the claimed method of treating a patient suffering from or predisposed to developing an inflammatory respiratory disorder.

With respect to Goldberg, applicants point out that the Examiner has cited Goldberg (journal article), without supplying a specific citation. Applicants have reviewed the references cited, as well as the 1449 forms submitted with the Information Disclosure Statements submitted by applicants, and it appears likely that the Goldberg reference intended by the Examiner is Goldberg, David M. et al. (1995) *A Global Survey of Trans-Resveratrol Concentrations in Commercial Wines,* Am. J. Enol. Vitic. Vol. 46, pp. 159-165. On this assumption, applicants have addressed the rejections using this reference.

The addition of Goldberg does not render the present claims obvious. Goldberg relates to a method of quantitating *trans*-resveratrol in wines, and merely mentions in the introduction of the paper that resveratrol is present in plants that have been "used in Japan as a source of herbal medications for the treatment of fungal, inflammatory and lipid disorders." The presence of trans-resveratrol in certain grape species is discussed as an antifungal agent providing protection for the grape. *See* the first paragraph on page 159 where Goldberg states "[m]uch interest has focused upon [*trans*-resveratrol's] presence in vines and grapes because of its potent antifungal activity and its correlation with resistance to fungal infection," and the first paragraph under "Discussion" on page 163, where Goldberg states "the characteristically thin skin of this cultivar

renders it especially prone to fungal infection and hence induction of *trans*-resveratrol synthesis." (citations omitted). Hence the brief mention of plants in Japan used "for the treatment of fungal, inflammatory and lipid disorders" is not suggestive of, nor is it enabling, for use of resveratrol for inflammatory respiratory disorders, or any other inflammatory disorder for that matter.

In addition, while Goldberg briefly mentions the possibility of using plants containing trans-resveratrol to treat fungal, inflammatory and lipid disorders, the reference at most makes the presently claimed method "obvious to try." This is, of course, not the proper standard for an obviousness analysis. *ACS Hospital Supply Corp. v. Travenol Laboratories, Inc.*, 2323 USPQ 577 (Fed. Cir. 1984). When a reference gives only general guidance as to the possible use of a technology or a general approach that seems to be a promising field of experimentation, with no indication of how the technology would be implemented, this is viewed as a mere invitation to experiment and the reference cannot, therefore, serve as a reference under 35 U.S.C. § 103. *In re O'Farrell*, 7 USPQ2d 1673 (Fed. Cir. 1988). Clearly, Goldberg falls within the category of references that represent mere "invitations" to experiment. The fact that there is no additional art on point, i.e., references that pertain to the use of resveratrol as an anti-inflammatory agent for respiratory disorders, is itself evidence of nonobviousness.

In addition, there would be no motivation to combine Fischer and Goldberg. As stated in *In re Oetiker*, 977 F.2d 1442, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992), "[i]n order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." In this instance, Goldberg and the applicant's field of endeavor are significantly dissimilar as are the particular problems with which the endeavors are concerned: Goldberg relates to a method of quantitating *trans*-resveratrol in wines; the instant claims relate to a method of treating inflammatory respiratory disorders. Therefore, Goldberg is not properly combinable with Fischer, and not applicable to the patentability of the claims.

The addition of Pezzuto does not correct these deficiencies. As discussed above with respect to the anticipation rejection of claim 29, Pezzuto is directed to a method for preventing or treating skin conditions, disorders or diseases using topical administration of resveratrol to the

skin. The combination of Pezzuto and Fischer, at best, suggests the use of resveratrol as a method of enhancing chloride transport in epithelial cells, including the skin. Therefore, Fischer in combination with Pezzuto does not teach or suggest all of the claim limitations, and hence the combination of references cannot render the present claims obvious.

With respect to the rejection of claims 16 and 17, applicants respectfully submit that the claims are patentable over Fischer, and that it is irrelevant whether Fischer discloses treating atopic asthma or non-atopic asthma. Fischer is directed to treatment of disorders due to defective chloride transport, and the combination of Fischer with any of the cited references does not teach or suggest all of the limitations of the pending claims.

With respect to the rejection of claims 21-23, applicants respectfully submit that the combination of Fischer, Pezzuto and Goldberg does not render the claims obvious. As discussed above, Goldberg is not properly combinable with either Fischer and Pezzuto and is not applicable against the pending claims. However, even if Goldberg were properly combinable with the other references, it still would not render the pending claims obvious because the combination of Fischer, Goldberg and Pezzuto does not teach or suggest all of the limitations of the pending claims. As stated above, Fischer is directed to treatment of disorders due to defective chloride transport, while the claims are directed to treatment of inflammatory respiratory disorders. These are distinguishable. Therefore the addition of Goldberg and Pezzuto does not render obvious claims to the treatment of inflammation resulting from occupational or environmental exposure to smoke, dust or allergens, because Fischer is still directed to enhancing chloride transport in epithelial cells.

With respect to the rejection of claims 26-28, the claims are not rendered obvious by the combination of Fischer and Pezzuto. Fischer is directed to a method of enhancing chloride transport in epithelial tissues. Modifying the methods of Fischer to include additional anti-inflammatory agents or antibiotics still does not teach or suggest all of the limitations of the pending claims. The addition of Goodman & Gilman's teaching to use antiasthmatics such as cromolyn sulfate and beta-adrenergic agonists or the administration of bronchodilators such as theophylline and salmetrol xinofoate, as taught by the American Drug Index also does not teach or suggest all of the limitations of the pending claims.

With respect to the rejection of claim 29, the combination of Goodman & Gilman with Fischer does not render this claim obvious. The teaching of Fischer to enhance chloride transport of epithelial cells in patients suffering from cystic fibrosis by administering flavones, isoflavones and other polyphenolic compounds, which may be resveratrol, combined with the teaching of Goodman & Gilman to administer glucocorticoids for asthma, does not result in all of the limitations of the pending claims. Claim 29 is directed to a pharmaceutical formulation for pulmonary administration for treatment of an inflammatory respiratory disorder, not for treatment of disorders associated with defective chloride transport. Therefore, Fischer in combination with Goodman & Gilman does not teach or suggest all of the claim limitations of claim 29.

For the foregoing reasons, applicants respectfully request the Examiner to reconsider and withdraw this ground of rejection.

CONCLUSION

In sum, applicants submit that the application comports with all requirements of 35 U.S.C. §§ 102 and 103 and that the pending claims define an invention that is patentable over the art. A Notice of Allowance is in order, and a prompt mailing thereof would be much appreciated.

Should the Examiner have any questions concerning this response, he is welcome to telephone the undersigned attorney at (650) 330-0900.

Respectfully submitted,

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APPENDIX A
AMENDMENTS

IN THE CLAIMS:

Please **amend** the claims as follows:

1. (Amended) A method for treating a patient suffering from or predisposed to developing an inflammatory respiratory disorder, comprising administering to the patient a pharmaceutical formulation that comprises a pharmaceutically acceptable carrier and a therapeutically effective amount of an active agent selected from the group consisting of resveratrol, pharmacologically acceptable salts, esters, amides, prodrugs ~~and~~ or analogs thereof, and combinations of any of the foregoing.

21. (Amended) The method of claim 1, wherein the disorder is a result of occupational or environmental exposure ~~is~~ to smoke, an organic or inorganic dust, or an allergen.

22. (Amended) The method of claim 21, wherein the disorder is a result of occupational or environmental exposure ~~is~~ to an organic or inorganic dust.

27. (Amended) The method of claim 26, ~~wherein the~~ wherein the additional active agent is selected from the group consisting of phosphodiesterase inhibitors, long acting β_2 adrenergic agonists, and combinations thereof.

29. (Amended) A pharmaceutical formulation for pulmonary administration for treatment of an inflammatory respiratory disorder, comprising a first active agent selected from the group consisting of resveratrol, pharmacologically acceptable salts, esters, amides, prodrugs ~~and~~ or analogs thereof, and combinations of any of the foregoing, and a second active agent selected from the group consisting of glucocorticoids, non-steroidal antiinflammatory drugs,

macrolide antibiotics, bronchodilators, and combinations thereof, and a carrier suitable for pulmonary drug administration.

30. (Amended) A dry powder pharmaceutical formulation for pulmonary administration, comprising an active agent selected from the group consisting of resveratrol, pharmacologically acceptable salts, esters, amides, prodrugs and analogs thereof, and a carrier suitable for pulmonary drug administration.

Please **add new** claims 31-37 as indicated above.

APPENDIX B
PENDING CLAIMS UPON ENTRY OF THIS AMENDMENT

1. A method for treating a patient suffering from or predisposed to developing an inflammatory respiratory disorder, comprising administering to the patient a pharmaceutical formulation that comprises a pharmaceutically acceptable carrier and a therapeutically effective amount of an active agent selected from the group consisting of resveratrol, pharmacologically acceptable salts, esters, amides, prodrugs or analogs thereof, and combinations of any of the foregoing.

2. The method of claim 1, wherein the active agent is *cis*-resveratrol or a pharmacologically acceptable salt, ester, amide, prodrug or analog thereof.

3. The method of claim 2, wherein the active agent is *cis*-resveratrol.

4. The method of claim 2, wherein the active agent is a conjugate of *cis*-resveratrol and a mono- or di-saccharide.

5. The method of claim 4, wherein the active agent is *cis*-resveratrol glucoside.

6. The method of claim 1, wherein the active agent is *trans*-resveratrol or a pharmacologically acceptable salt, ester, amide, prodrug or analog thereof.

7. The method of claim 6, wherein the active agent is *trans*-resveratrol.

8. The method of claim 6, wherein the active agent is a conjugate of *trans*-resveratrol and a mono- or di-saccharide.

9. The method of claim 8, wherein the active agent is *trans*-resveratrol glucoside.

10. The method of claim 1, wherein the active agent comprises a mixture of *cis*-resveratrol and *trans*-resveratrol.

11. The method of claim 1, wherein the active agent is delivered orally.

12. The method of claim 1, wherein the active agent is delivered by pulmonary administration.

13. The method of claim 1, wherein the active agent is delivered parenterally.

14. The method of claim 13, wherein the active agent is delivered to the alveoli.

15. The method of claim 1, wherein the disorder is asthma.

16. The method of claim 1, wherein the disorder is atopic asthma.

17. The method of claim 1, wherein the disorder is non-atopic asthma.

18. The method of claim 1, wherein the disorder is COPD.

19. The method of claim 1, wherein the disorder is alveolitis.

20. The method of claim 1, wherein the disorder is interstitial lung disease (ILD).

21. The method of claim 1, wherein the disorder is a result of occupational or environmental exposure to smoke, an organic or inorganic dust, or an allergen.

22. The method of claim 21, wherein the disorder is a result of occupational or environmental exposure to an organic or inorganic dust.

23. The method of claim 22, wherein the organic or inorganic dust is derived from one or more materials selected from the group consisting of silica, asbestos, beryllium, coal, carbon, wood, starch, sugar, flour, synthetic polymers, cellulosic materials, clay concrete, lime and earth.

24. The method of claim 1, further comprising the co-administration of an additional active agent.

25. The method of claim 24, wherein the formulation further includes an additional active agent.

26. The method of claim 25, wherein the additional active agent is selected from the group consisting of glucocorticoids, non-steroidal antiinflammatory drugs, macrolide antibiotics, bronchodilators, leukotriene receptor inhibitors, cromolyn sulfate and combinations thereof.

27. The method of claim 26, wherein the additional active agent is selected from the group consisting of phosphodiesterase inhibitors, long acting β_2 adrenergic agonists, and combinations thereof.

28. The method of claim 27, wherein the additional active agent is selected from the group consisting of theophylline, salmetrol xinafoate, and a combination thereof.

29. A pharmaceutical formulation for pulmonary administration for treatment of an inflammatory respiratory disorder, comprising a first active agent selected from the group consisting of resveratrol, pharmacologically acceptable salts, esters, amides, prodrugs or analogs thereof, and combinations of any of the foregoing, and a second active agent selected from the group consisting of glucocorticoids, non-steroidal antiinflammatory drugs, macrolide antibiotics,

bronchodilators, and combinations thereof, and a carrier suitable for pulmonary drug administration.

30. A dry powder pharmaceutical formulation for pulmonary administration, comprising an active agent selected from the group consisting of resveratrol, pharmacologically acceptable salts, esters, amides, prodrugs and analogs thereof, and a carrier suitable for pulmonary drug administration.

31. A pharmaceutical formulation for treatment of an inflammatory respiratory disorder, comprising a first active agent selected from the group consisting of resveratrol, pharmacologically acceptable salts, esters, amides, prodrugs or analogs thereof, and combinations of any of the foregoing, and a second active agent selected from the group consisting of glucocorticoids, bronchodilators, leukotriene receptor inhibitors, cromolyn sulfate and combinations thereof.

32. The formulation of claim 31, wherein the formulation further comprises a carrier suitable for pulmonary drug administration, and the formulation is administered via inhalation.

33. The formulation of claim 31, wherein the formulation is administered orally or parenterally.

34. The formulation of claim 31, wherein the inflammatory respiratory disorder is selected from the group consisting of asthma, atopic asthma, non-atopic asthma, COPD, alveolitis and ILD.

35. The dry powder formulation of claim 30, wherein the carrier is a pharmaceutical sugar.

36. The dry powder formulation of claim 30, wherein the particles of the powder have a diameter from about 0.1 μm to about 65 μm.

37. The formulation of claim 29, wherein the inflammatory respiratory disorder is selected from the group consisting of asthma, atopic asthma, non-atopic asthma, COPD, alveolitis and ILD.

APPLICATION DATA SHEET

APPLICATION INFORMATION

Application Number::	09/964,108
Filing Date::	October 19, 2000
Application Type::	Regular
Subject Matter::	Utility
CD-ROM or CD-R?::	
Number of CD Diskettes?::	
Number of Copies of CDs::	
Sequence Submission?::	
Computer Readable Form::	
Number of Copies of CFR::	
Title::	ADMINISTRATION OF RESVERATROL TO TREAT INFLAMMATORY RESPIRATORY DISORDERS
Attorney Docket Number::	7500-0010
Request for Early Pub?::	No
Request for Non-Pub?::	No
Suggested Drawing Figure::	N/A
Total Drawing Sheets::	0
Small Entity?::	No
Petition Included?::	No
Petition Type::	
Licensed US Govt. Agency::	
Contract or Grant Numbers::	
Secrecy Order in Parent?::	

APPLICANT INFORMATION

Inventor Authority Type::	Inventor
Primary Citizenship Ctry::	United Kingdom
Status::	Full Capacity
Given Name::	Louise
Middle Name::	Elizabeth
Family Name::	Donnelly
Name Suffix::	n/a
City of Residence::	London
State or Province::	
Country of Residence::	England
Postal or Zip Code::	W5 4NE

Inventor Authority Type::	Inventor
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Status::	Full Capacity
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Middle Name::	John
Family Name::	Barnes
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Correspondence Customer

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REPRESENTATIVE INFORMATION

Representative Customer Number::	23980	

DOMESTIC PRIORITY INFORMATION

Application::	Continuity Type::	Parent Application::	Parent Filing Date::

FOREIGN PRIORITY INFORMATION

Country::	Application Number::	Filing Date::	Priority Claimed::

ASSIGNMENT INFORMATION

Assignee Name::	Imperial College Innovations Limited
Street of Mailing Address::	Sherfield Building
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